(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 October 2001 (18.10.2001)

PCT

(10) International Publication Number
WO 01/76460 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number: PCT/US01/11847

(22) International Filing Date: 11 April 2001 (11.04.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/196,154 11 April 2000 (11.04.2000) US

(71) Applicants and
(72) Inventors: **ZIONE, Rhoda** [US/US]; 6525 Belcrest Road, Box 1625, Hyattsville, MD 20782 (US). **HOUSE, Arthur** [—/US]; 5813 Ningate Drive, Bethesda, MD 20817 (US).

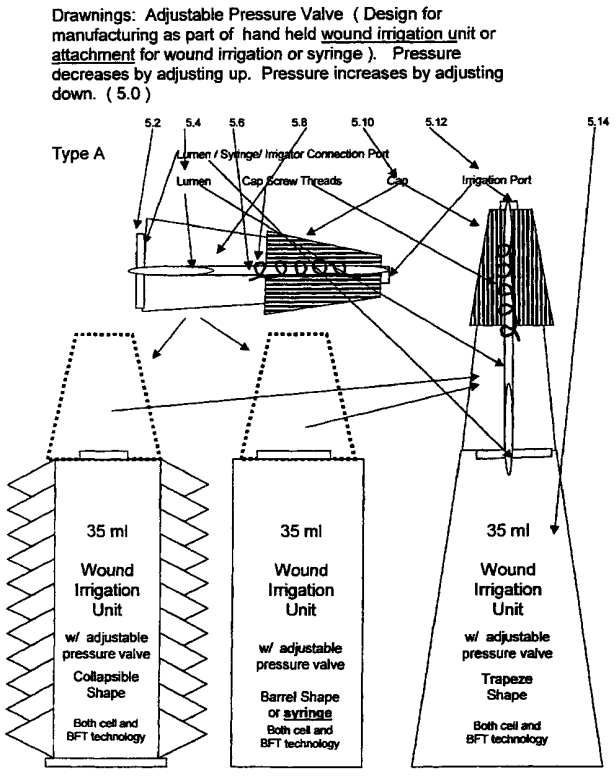
(81) Designated States *(national)*: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PATIENT MANAGEMENT NURSING SOFTWARE; WOUND OXYGENATION DEVICES: OXY-PAD AND CAM; AND ADJUSTABLE FLOW WOUND IRRIGATION DEVICE



(57) Abstract: The present invention relates to nursing software and medical equipment for wound care. This Patient Management Nursing Software system invention is to provide an effective computer software management system for clinical management of nursing in the delivery of patient services which include: intake, patient education, positive nurse-client interactions, follow-up and discharge planning. The described invention fosters empathy and "thoughtfulness" in "provider-client" relations to preserve the "art" of bedside care. The medical equipment for wound care inventions include adjustable pressure irrigators (Fig. 5 and 6), oxygen infusion applicators (Fig. 1, 2, 3, 7 and 8), deep wound irrigation kits (Table: Wound Kits) and a mechanic device for irrigation (Fig. 4). Wounds effectively managed reduce wound complications and costs. These inventions all are designed to promote wound healing, reduce costs and material waste and prevent infections from the use of contaminated equipment use. Wound oxygenation therapies provide vent ports sufficient to deliver O2 to the tissue to enhance tissue perfusion. Adjustable, disposable plastic wound irrigation devices allow for the low pressure irrigation. This thereby allows for vascular stimulation and necrotic tissue removal from the wound surface and thus promotes healing. Wound irrigation kits further enhance both the clients and clinical practitioners skills by pre-organizing the equipment needed for the procedure and reducing material waste and infections from equipment contamination. The use of the battery or electrically operated mechanic device enables the small or infirm persons to be assisted in irrigating a wound with ease.

WO 01/76460 A2

Patient Management Nursing Software; Wound Oxygenation Devices: Oxy-Pad & Cam; and Adjustable Flow Wound Irrigation Device

DESCRIPTION

The present invention relates to medical services for wound and patient service management tools for nurses and physicians. The Patient Management Nursing Software system invention is to provide an effective computer software management system for clinical management of nursing in the delivery of patient services which include: intake, patient education, follow-up and discharge planning. Current software products do not facilitate nurse management for a patients' clinical needs. This software is designed to allow a nurse to receive, based on the patient's ICD9 codes that are entered during the admissions process, information about a patient before the patient even arrives on the nursing floor so as to be better ready for that patient, and to have care plan options, discharge planning factors, patient education materials, automatic links to selected Internet and network resources available upon arrival of the patient. Moreover, there is a need to help nurses deal with the daily pressures of their profession, for example, in circumstances where a patient dies. The software provides inspirational messages and messages of support and guidance for the nursing staff and condolences for the nurse to give the patient's family. Furthermore, much has been lost in the "bedside" mannerism of both physicians and nurses today. The described invention fosters empathy and "thoughfulness" in "nurse-client" relations. It allows nursing staff to print or automatically send an electronic (email) care message to a patient or family members, whether it is for a special occasion such as a birthday or anniversary, or merely words of encouragement or greeting to lift a patients' spirits.

The design of the wound irrigation is designed to meet the clinical practice guidelines of the Food and Drug Administration that suggest 4-12 PSI should be used as the therapeutic pressure range for wound irrigation. Additionally, it allows for further investigation of which ranges of pressure are more therapeutic for "which?" types of wounds.

Wounds respond well to exposure to oxygen. However, no present intermittent, wound oxygenation therapies with disposable infusion systems exit or wound dressings which provide vent ports sufficient to deliver O2 while in a closing bandage system. By directly affording a means of ingress for oxygen or other gases and a means for venting effluent gases, the described wound dressing can meet those needs. Additionally, when used without an exhaust vent in the dressing, the assumption is that, the invention may provide for a means for localized hyperbaric therapy to tissues, if determined to be efficacious by the healthcare provider.

By adjusting the size of the delivery lumen of a disposable plastic wound irrigation device, the pressure and rate of flow of liquid used to irrigate a wound may be adjusted efficiently. The use of a pressure activated membrane or valve within the wound irrigation device can assure delivery of liquids at the desired pressure of 4-12 PSI, without the large variation and pressure, either too high or too low, as exists with a unit used for irrigation that lacks these regulation devices.

The use of the battery or electrically operated pressure device as described above has the advantage of delivery of liquid for wound irrigation purposes at a selected pressure while maintaining sterility of the liquid solution used. A further advantage of the device is that fatique that may result in the case of weak, small, aged, or infirm persons attempting to irrigate a wound is avoided by use of the mechanical device for delivery of the irrigation fluid as opposed to the use of a hand-held squeezed device.

This Application further expands informatic methodologies and technologies invented by Rhoda Zione (Utility Application – Title: The Wound Manager System and Wound Dressing – Filing Date – Jan. 20, 2000). The inventor noted that current wound care and, more generally, medical treatment administered by nursing and paraprofessional nursing staff is highly variable and subject to high rates of non-compliance in following prescribed medical procedures and accepted nursing protocol. The inventor observe two problematic areas: 1) poor computer literacy skills of nursing and clinical staff personnel, especially with text computing. Therefore, there appeared to be a need to make computing for clinical management more "user friendly and visual." 2) the inventor noted a nationwide "epidemic" of poor "morale" (spiritual and emotional) among nursing personnel which has grossly effected nurse motivation and the optimal virtues of compassion and excellence of skill in "nurse-patient" relationships. Perhaps these conditions are reflected from the gross understaffing or "frequent turn over of staff at most hospitals."

To address these needs, the inventor designed:

1) A Patient Management Nursing Software system that specifically structures nursing and support technical staff care regimens in a hospital or nursing home environment in order to improve nursing and support staff care to patients. System can be operational from a touch screen, PC, Network, Palm Pilot or internet computing technology. The Touch Screen features have touch directives for (which include but are not limited to) care plan, discharge / patient education, and motivational / inspirational message development. First, the system is prompted to alert the nursing personnel upon a patient's admission (a) the arrival of a new patient, including room location and (b) the admitting diagnoses, with an indication of, for example, the ICD9 code (c) treatment regimen (i.e.

surgery, therapy schedules). Thereafter, based upon the ICD9 code or other diagnosis code or codes, the Patient Management Nursing Software has select automated or self-create (manual) features for choosing: (c) a set of care plan options for the patient, (d) generating discharge planning factors, (e) generating patient education information for instructing the patient on proper care pertinent to the patient's condition, (f) providing automatic, embedded, or hyperlinked access to selected Internet or private network resources pertinent to the patient's condition, cultural or language needs, (g) generating motivational messages and messages of support to nurses, nursing technicians and other care personnel, and to patients, and (h) the software has a multi-lingual capability.

2) This application also presents new technologies for enhancing wound management invented by : Rhoda Zione and Art House which: 1) are wound oxygenation devices for direct oxygen infusion to wound tissue and 2) are adjustable pressurized delivery systems for wound irrigations. Also, in assessing the care currently given to wounds, the inventors noted: 1) the increased healing factors of patient's on ventilators; 2) the "lack" of clinical data / research to investigate the direct infusing of oxygen to wound tissue; and 3) the need to enhance aeration of wound tissue. Additionally, the inventors noted the lack of methodologies to adjust wounds irrigation pressure so that the delivery of a prescribed irrigant such as sterile saline or other solution can be delivered at a constant pressure between 4-12 PSI of pressure, which is the FDA recommended pressure for wound irrigating. Existing systems often deliver saline at inadequate pressures, thereby failing to remove dead tissue and exudate and failing to stimulate circulation to promote healing.

2) The Wound Oxygenation Devices: Oxy -Cam & Pad invention consists, generically, of soft disposable plastic that has internal one or more vent ports for direct infusion of oxygen to the wound bed and one or more external vent ports for the removal of gases for the wound bed. The Oxy-Cam is more a soft molded disposable plastic much like a mouth / nasal mask for inhalation therapy. It is designed to fit as a "tent-cam" over the wound with a "one-way" flow valve into the cam that allows for tube connection both inside and out. The external valve has a connection port for connecting, by tubing, to the direct flow values of the oxygen administration units. The internal valve has a connection port for connecting tubing for direct flow of the oxygen into a closed dressing system via a "window" or "macro port." Oxy-Pad is more a soft molded disposable plastic much like that which is used in urinary bag manufacturing. It's molding design "may or may not" allow for inflation of the "lift rafts" to facilitate oxygen delivery. This system can be designed to have the "lift rafts" pre-inflated. It is designed have adjustable fit capabilities to be used as if an O2 infusing pad –"flat lie" such as over a buttock or hip area or secured and wrapped around an extremity such as a arm or leg. Both the Pad and Cam can be manufactured in different sizes to accommodate the wound size. The implication is that O2 directed applied to wound tissue, with or without humidification, will help to promote healing by increasing tissue perfusion. The Oxy-Pad has the same "one-way" flow for the oxygen administration the same as the Oxy-Cam. Both the Pad & Cam can be used with a "flow canula... a disposable tube consisting of many holes... that can be used to direct O2 into a wound dressing system with a "window or macro port" aperture or with absorption infusion dressings which are place between the cam and the patient's skin and allow for maximal access to the wound. These "window or macro port" aperture wound dressing materials having a length, a width, a thickness, and an edge circumnavigating the sheet of wound dressing. Length and

width of the wound dressing is of sufficient dimension to cover and protect a particular wound. The sheet of wound dressing has at least two apertures cut therein and extending therethrough. At least one of these apertures has a width being about 0.25 cm to about 1.25 cm and the length being about 0.25 cm to about 3.5 cm. Said aperture is located at least 2.5 cm from the edge of the sheet of wound dressing. At least one other aperture in the wound dressing is configured to connect to, or to be permanently affixed to, a tube, catheter, or other device for introducing air, oxygen, or some other gas or a mixture of gases, under the wound dressing and in contact with the wound tissue so as to facilitate aeration or oxygenation of the wound to promote healing.

Additionally, it can be manufactured with or without a timing device for monitoring of the therapy regimen. The wound dressing may also be configured with or without exhaust vents, so as to encompass and contain all or part of a human or animal limb.

3) **Zione and House also designed an "adjustable pressure activating valve"** which delivers between approximately 4-12 PSI of pressure through fittings that varies the size of the opening or lumen during irrigation. This valve is designed to be placed on wound irrigation units for purposes of delivering a liquid within a pre-set pressure range for wound irrigation. It can be manufactured as an attachment to a syringe or irrigation device. The "adjustable pressure activating valve" can also be manufactured in the design of single unit, hand-held, plastic /disposable wound irrigation system which can be modified for blow-fill, cell-fill or similar technology, wherein a membrane or the referenced membrane or valve can be set to open at a pre-determined, desired pressure. These "adjustable pressure activating valve" have two designs. One that "twist" up and down. Twisting up opens to decrease pressure. Twisting down closed to increase pressure. The second is a dialing

structure with 4 positions and numbered 1, 2, 3 and 4. Position 1 is least resistance affording the minimal range (not less than 4 PSI) of pressure. As the numbers increase through, 2 and 3 to Position 4, so does the delivery of pressure which affords the maximal range (not more than 12 PSI) of pressure.

4) Inventors, Zione and House, also designed a means for electronic delivery of the single, hand held, wound irrigation device. This mechanical apparatus can be used by persons with limited neuro-muscular stamina or abilities who can not manually manipulate the hand-help disposable unit. The disposable wound irrigation system/unit can then be placed into a small, stationary or portable, battery-operated or electric-powered which will then compress its contents at a desired pressure for the delivery of effective wound irrigation. The device described may have a dial, gauge, or other common means to select the pressure at which the liquid will be delivered.

BRIEF DESCRIPTION OF THE DRAWNINGS

Drawing 1.0 – Wound Oxygen Infusion Pad.

1.2 Illustrates the (wound contact surface) of the infusion cam with the oxygen infusion port/holes.

1.4 Illustrates the closure strap

1.6 Illustrates the hole through which the closure strap engages.

1.8 Illustrates the "one-way" oxygen flow valve which allows for external or internal attachments to the oxygen administration unit.

1.10 Illustrates the air – filled cells to promote comfort.

1.12 Illustrates the molded dividers of the air-filled cells.

1.14 Illustrates the external vent port.

1.16 Illustrates timing device.

Drawing 2.0 – Wound Oxygen Infusion Cam.

2.2 Illustrates the circular cam hood

2.4 Illustrates the "oneway" flow valve with external and internal attachment valves

2.6 Illustrates the external vent

2.8 Illustrates the strap to secure cam to extremity

2.10 Illustrates the opening / hole for the engagement of the securing strap

2.12 Illustrates timing device.

Drawing 3.0 – Wound Oxygen Infusion Cannula.

3.2 Illustrates the open end

3.4 Illustrates the infusion port / opening

3.6 Illustrates the oxygen infusion canula

Drawing 4.0 – Mechanical Delivery Device for Disposable Wound Irrigators

4.2 Illustrates the off and on switch located in the middle / lateral of the motor dome.

4.4 Illustrates the latch release button to open the device and insert the irrigator

4.6 Illustrates the latch which secures the dome to the cylinder.

4.8 Illustrates the view port / area of the device where the irrigator can be observed.

4.10 Illustrates the motorized dome of the device

4.12 Illustrates the ascending and descending plunger from the motorized dome.

4.14 Illustrates the irrigation nozzle port

4.16 Illustrates the distal irrigation engagement compression disc of the plunger

4.18 Illustrates the attachment hinge of the dome to the cylinder

Drawing 5.0 – Adjustable Pressure Valve (Twist Top)

5.2 Illustrates the irrigator / syringe attachment engagement port

5.4 Illustrates the lumen port

5.6 Illustrates the cap screw threads

5.8 Illustrates the apparatus cam on which the "twist" top sits

5.10 Illustrates the "twist" top cap

5.12 Illustrates the irrigation port

5.14 Illustrates the irrigation unit

Drawing 6.0 – Adjustable Pressure Valve (Dial Top)

6.2 Illustrates the adjustable dial apparatus

6.4 Illustrates the irrigator or syringe attachment port

6.6 Illustrates the short sheath cam

6.8 Illustrates the lumen.

6.10 Illustrates the long sheath cam attached to irrigation unit

Drawing 7.0 – Oxygen Infusion Absorption Dressing for Wound Oxy-Pad

7.2 Illustrates the absorption dressing

7.4 Illustrates opening in the dressing to facilitate oxygen infusion

Drawing 8.0 – Oxygen Infusion Absorption Dressing for Wound Oxy-Cam

8.2 Illustrates the absorption dressing

8.4 Illustrates opening in the dressing to facilitate oxygen infusion

Table: Wound Irrigation Kits

1 Illustrates packaging contents for wound irrigator

2 Illustrates packaging contents for wound irrigator with wound catheter

3 Illustrates packaging contents for wound irrigator with wound cleanser

4 Illustrates packaging contents for wound irrigator with wound catheter and cleanser

5 Illustrates packaging contents for Deep Wound System with 2 wound irrigators with or without a wound catheter, cleanser or both

6 Illustrates packaging contents for Deep Wound System with 3 wound irrigators with or without a wound catheter, cleanser or both

7 Illustrates packaging contents for Deep Wound System with 4 wound irrigators with or without a wound catheter, cleanser or both

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The Patient Management Nursing Software provides computerized guidance and structure for nurses and nursing technicians engaged in patient care and management, beginning with patient admission, through patient discharge and home care. It comprises:

1) a computer generated nursing plan, including but not limited to, regimens of disease or condition-specific protocols based upon the patient's admitting diagnosis as specified in the patient's ICD9 codes;
2) computer generated pictorial guides (informatic directives) to make treatment and management regimens visual;
3) a computer generated nursing discharge plan based upon the patient's admitting diagnosis as specified in the patient's ICD9 codes;
4) computer generated instructional, training, and home care information for the nurse, technician, and/or patient based upon admitting diagnosis as specified in the patient's ICD9 codes or subsequent observations or orders by a physician;
5) computer generated inspirational or supportive messages to the nursing staff or technical personnel to uplift their morale or to help staff deal with the stresses of the job;
6) computer generated inspirational or supportive "get well" messages to the patient to uplift the patients' morale.
7) "touch pad" computing capabilities facilitates "user friendliness."

Items 1-3, above, may be generated immediately upon patient admission and sent directly (through computing dispatch or fetch capabilities) to the receiving nursing station to allow nursing staff familiarity with a patients' condition before the patient even reaches the care unit. Each of the foregoing standardized features generated by the computer program upon admission of the patient is modifiable after patient admission to reflect ongoing assessment of the patients' condition or disease state.

An example of the operation of the Patient Management Nursing Software program for provision of a clinical pathway for the treatment and management of wounds would be the following:

1) computer generated pictorial guides (informatic directives) to make treatments visual;

2) computer generated treatment regimens of seven medical protocols:

   a) – Protocol 0: skincare w/lotions or creams.

   b) – Protocol 1: Iodosorb/Iodoflex Tx for drainage/infection management for persons who are not allergic to Iodine.

   c) – Protocol 2: Hydrosorb Tx for drainage/infection management for persons who are allergic to Iodine.

   d) – Protocol 3: Hydrogel Ointments when possible for hydration therapy.

   e) – Protocol 4: Accuzyme ointment for enzymatic debridement.

   f) –Protocol 5: Poly-Mem foam/sponge for hydration and infection management.

   g) – Protocol 6: Poly-Mem Calcium Alginate foam/sponge for hydration drainage and infection management.

These protocols are supported by the software program, e.g., in the case of wound management, by a medical record documentation system that automatically generates any or all of the following:

a) Nursing care plan

b) Pictorial care guides for nursing and technical staff

c) Nursing discharge plan

d) physician order

e) treatment kardex

f) wound number log

g) wound consultation report

h) wound care addendum to the daily flow sheet

i) wound tracking system

j) photo progress report

k) treatment recommendations specific to the nature and stage of the wound involved

l) messages of encouragement, appreciation, and inspiration to the nursing and technical staff to boost morale and professionalism

m) messages of encouragement, compassion, and care for patients

n) educational, training, and home and self-care information for patient use or use by nursing and technical staff to train patients relevant to the patients' condition

The step-by-step approach to nursing care described by our invention, as appropriate for the specific patient condition beginning with ICD9 or similar codes at the time of patient admission, affords clarity, simplicity, and uniformity of nursing care, by utilizing picture guides and computerized treatment regimens. The software program of our invention enables the delivery of a uniform, standardized level of nursing care to similarly situated patients dependent on their condition as determined by a physician upon admission or as observed thereafter and modified. It also, through internet or dial-up access, affords physician immediate access for retriving information regarding patients' admission status, on-going progress and care regimens.

The Wound Oxygenation Devices: Oxy - Cam & Pad invention where stated is innovatively designed to promote wound healing by enhancing the tissue perfusion of the open wound. These devices pioneer new assumptions that increased oxygenation of open wounds cuts wound healing time and enhances treatment regimens. Wound oxygenation therapy may be implemented with or without humidifying the O2.

The single unit, hand-held, plastic/disposable wound irrigation system, which can be modified for manufacture through blow-fill or similar technology, contains a membrane or pressure activated valve placed within or as a separate attachment for the unit for purposes of delivering a liquid within a pre-set pressure range for wound irrigation. The referenced membrane or valve is set to open at a pre-determined, desired pressure.

The wound irrigation variable opening device, with or without a pressure-activated membrane or pressure valve placed in the unit, is drafted to be used in combination with a single unit,

hand-held, squeezable device of disposable plastic, pre-filled with 35 ML of normal saline solution or other liquid. The device is made to variably open and close by means of a threaded female cap piece that is easily twisted down over the threads of a male piece in order to variably open and close the aperture or a dialing device which constricts as it is advanced or dialed from 1 to 4 such that Position1 provides the minimal amount of pressure and Position4 provides the maximal amount of pressure. These devices can also be manufactured or packaged in kits with wound cleaning products to facilitate patient compliance with the wound care regimen.

When used in conjunction with the electrically powered delivery device described herein for the delivery of liquid with a constant pressure, the disposable wound irrigation unit may be utilized without the variable opening adjustment described above or the membrane or pressure valve as described for hand-held irrigation.

The small, stationary or portable, battery-operated or electric-powered device into which the single unit, squeezable or collapseable device of disposable plastic, pre-filled with 35 ML of normal saline solution or other liquid is placed and which device delivers the contents of the wound irrigation system at a desired pressure for effective wound irrigation, is drafted to have a dial, gauge, or other common means to select the pressure at which the liquid will be delivered. The device operates by "a switch" to start the mechanic function of applying pressure to the pre-filled liquid container by means of a roller, piston, or plate, which in turn forces the liquid out of the container with a pressure sufficient to be effective for wound irrigation.

The software described would, for the first time, be geared toward nursing management of patient care regimens from admission through discharge to homecare. It is a novel feature of the software that, for the first time, it promotes high standards of nursing practice through the utilization of a computer program that includes but is not limited to "touch screen" technology by (a) guiding nurses or other healthcare providers through the steps of accepted, proper nursing practice appropriate for an individual patient's condition and (b) enhancing the morale of the nursing staff at times of stress or emotional difficulty. It is a novel feature of the software that, for the first time, it permits a methodology to improve patient morale and attitude as well as patient training regimens through a computer program solution. The pressure controlled wound irrigator is novel and provides a disposable irrigation system for pressure therapy that allows the user to adjust the control the amount of pressure applied to a wound during treatment. Additionally, for the first time, the wound irrigator mechanical apparatus, through battery or electrical power, would permit physically incapacitated or weak individuals to apply saline or other liquids during wound treatment at therapeutic amounts of pressure.

The wound oxygenation devices further enhances patient therapy by providing, for the first time, a means of delivering oxygen or some other gas directly to a wound surface in a sterile, controlled manner for the purpose of enhancing tissue perfusion. It would also permit "localized" hyperbaric therapies to be applied to a wound as opposed to the complete enclosure of the patient in a hyperbaric chamber or oxygen tent with resultant savings in costs and increased in patient safety. Additionally, it can be manufactured with or without a timing device for monitoring of the therapy regimen.

CLAIMS

1. a patient service management software for nurses and physicians., comprising the steps of:

a) inputting health data;

b) inputting admitting diagnosis including ICD9 disease code data;

c) inputting physical assessment data;

d) permitting a user to formulate a treatment protocol from the group consisting of a protocol formulated in automated fashion, a protocol formulated by manual selection, and a protocol formulated in semi-automated fashion;

e) generating and outputting documentation for a computer generated nursing care plan, including but not limited to, regimens of disease or condition-specific protocols based upon the patient's admitting diagnosis as specified in the patient's ICD9 codes;

f) displaying said plurality of treatment protocols including nursing care plans, or critical pathways;

g) displaying reference material related to said plurality of treatment protocols including nursing care plans including critical pathways;

h) reviewing and confirming the formulated protocol;

i) displaying said plurality of treatment pictorial guides (informatic directives);

j)..displaying reference material related to said plurality of pictorial guides (informatic directives);

k) generating and outputting computerized pictorial guides (informatic directives) to make treatment and management regimens visual;

l) reviewing and confirming the formulated pictorial guides;

m) displaying said plurality of nursing discharge plan based upon the patient's admitting diagnosis as specified in the patient's ICD9 codes;

o) displaying reference material related to nursing discharge plan based upon the patient's admitting diagnosis as specified in the patient's ICD9 codes;

p) generating and outputting computerized nursing discharge plan based upon the patient's admitting diagnosis as specified in the patient's ICD9 codes;

q) reviewing and confirming the formulated nursing discharge plan;

r) generating and outputting computerized instructional, training, and home care information for the nurse, technician, and/or patient based upon admitting diagnosis as specified in the patients' ICD9 codes or subsequent observations or orders by a physician;

t) reviewing and confirming the formulated instructional materials;

u) displaying computerized inspirational or supportive messages;

v) generating and outputting computerized inspirational or supportive messages to the nursing staff or technical personnel to uplift their morale or to help staff deal with the stresses of the job;

w) displaying computerized inspirational or supportive messages "get well" messages for the patient;

x) generating and outputting computerized inspirational or supportive "get well" messages to the patient to uplift the patients' morale.

y) inputting and outputting with "touch pad" computing capabilities to facilitate "user friendliness."

z) outputting a plurality of pictorial guides for disease management strategies; and

z-1) outputting a protocols designed for specific ICD9 code disease management for nursing care plans including critical pathways, wherein the protocol includes instructions for diet, signs and symptoms of disease exacerbation, medications, exercise and activities.

2. a adjustable pressure wound irrigation device comprising:

a) a receptacle for containing and dispensing fluid for wound irrigation;

b) an adjustable, device for therapeutic pressure application in wound irrigation which is attached to said receptacle and functions to:

(1) adjust to multiple positions to increase or decrease pressure, and

(2) directs the fluid stream from the said receptacle through an apparatus to facilitated the pressurized application of fluid;

c) a method of packaging fluids for said receptacle that dispenses a single irrigation application, wherein the said receptacle protects the fluid contents from contamination to prevent infection to wound tissue, provides single irrigation application to prevent material waste, promotes therapeutic irrigation for hydration, vascular stimulation and removal of drainage and necrotic tissue from wounds.

3. a method of stimulating wound healing comprising of the direct application of oxygen to wound tissue, whereby wound healing is promoted.

4. a device for applying oxygen directly to wounds which comprises:

a) apparatuses for infusing oxygen directly to wound tissue;

b) apparatuses for external venting of gases from wound tissue;

c) apparatuses for securing or strapping the device to the body;

d) apparatuses for infusing oxygen through an opening into dressing coverings

that are non-adhering or adhering, whereby tissue perfusion is stimulated to promote wound healing and reduce infection.

5. an absorption dressing with an opening for use as a treatment barrier or shield to the wound surface and margins comprising:

a) aseptic material for absorption;

b) porous openings for air-flow to affected and non-affected areas of the said aseptic material borders;

c) central opening in the said aseptic material to facilitate direct access to the affected tissue for therapeutic interventions, whereby treatment interventions are facilitated in a manner to reduce infection and tissue drainage is managed.

6. a hand held mechanical device comprising:

a) apparatuses for turning power on and off;

b) chamber for holding disposable irrigators;

c) apparatuses for securing irrigating devices in place for compression;

d) motorized apparatuses for compressing irrigating devices;

e) apparatus port for directing fluid for the irrigation process; whereby persons with physical impairments may facilitated pressurized wound irrigation procedures with ease.

7. a method of packaging equipment and medical supplies for wound irrigation comprising of:

   a) a receptacle tray container for depositing irrigation solutions and wound debri during irrigation;

   b) one or more disposable wound irrigators placed in the said receptacle container;

   c) one or more absorption materials placed in the said receptacle container;

   d) one or more sterile barriers placed in the said receptacle container;

   e) zero or more catheter canulas placed in the said receptacle container;

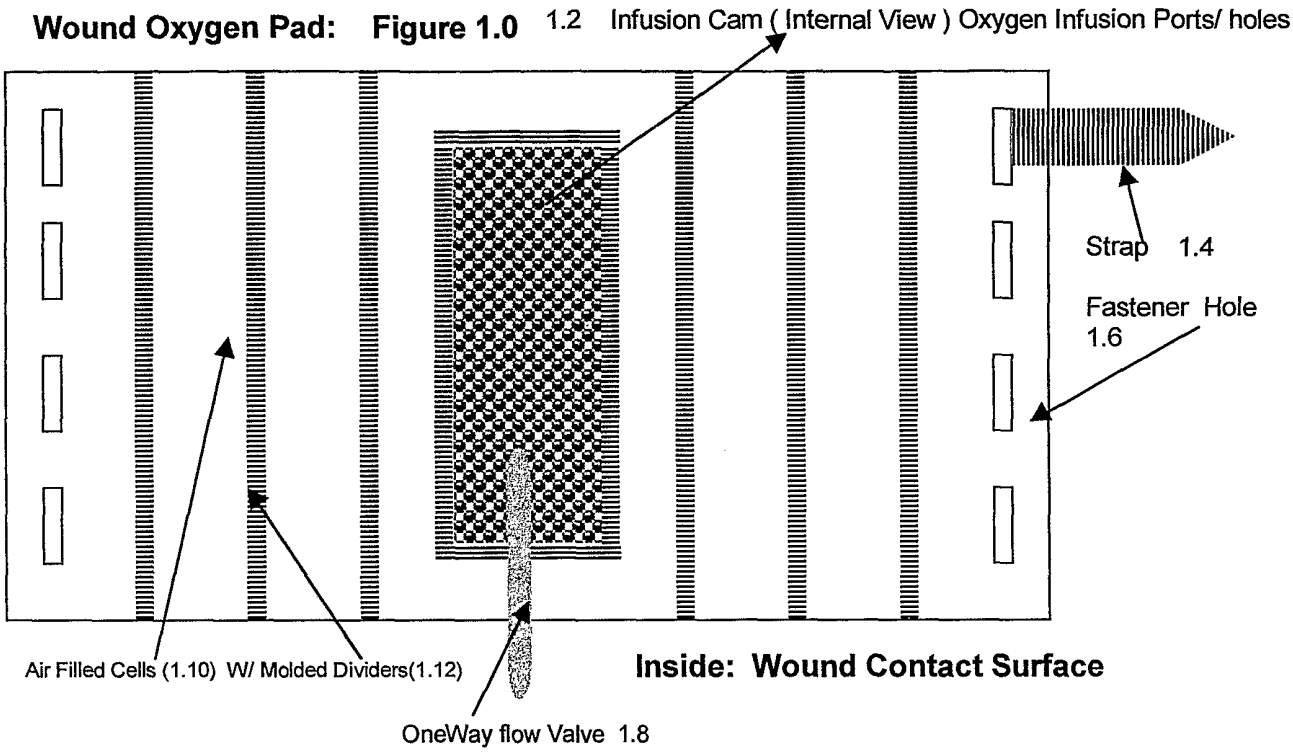
   f) zero or more cleansers placed in the said receptacle container;

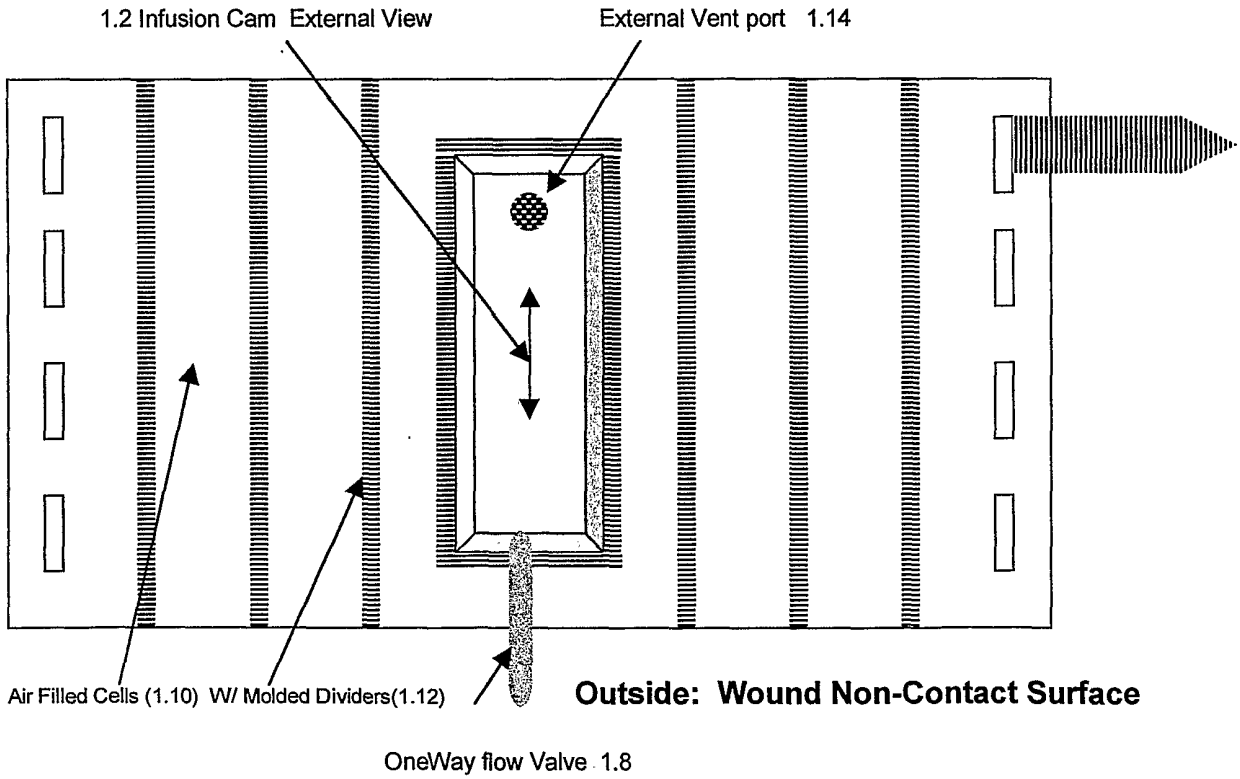
   g) zero or more gloves placed in the said receptacle container,

   h) aseptic packaging of the said receptacle container and all the said medical supplies, whereby wound irrigation is facilitated in an aseptic manner to prevent infection from contamination; material waste is reduced by using appropriate amounts and supplies for the treatment; and independence and efficiency is fostered in persons providing wound irrigation treatments.

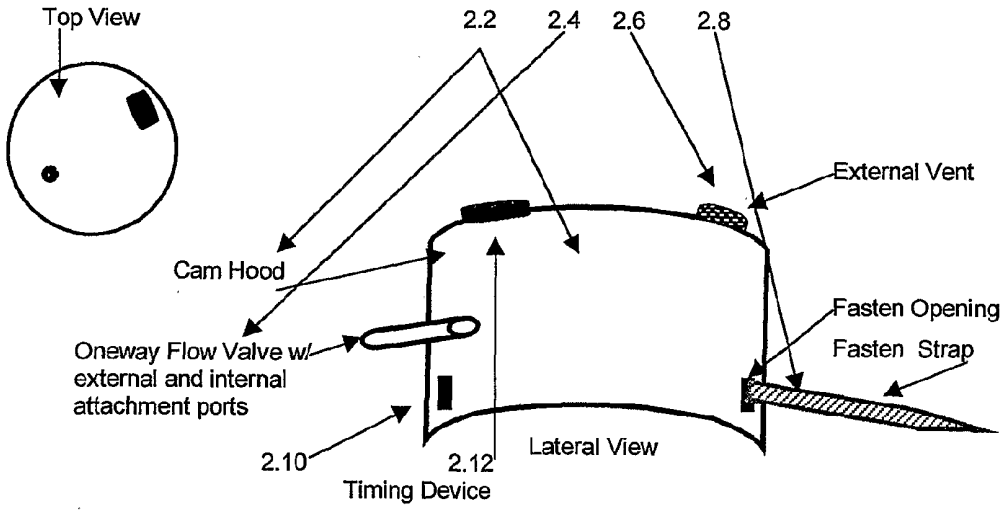
Drawnings: Wound Oxygen Pad

Wound Oxygen Pad: Figure 1.0



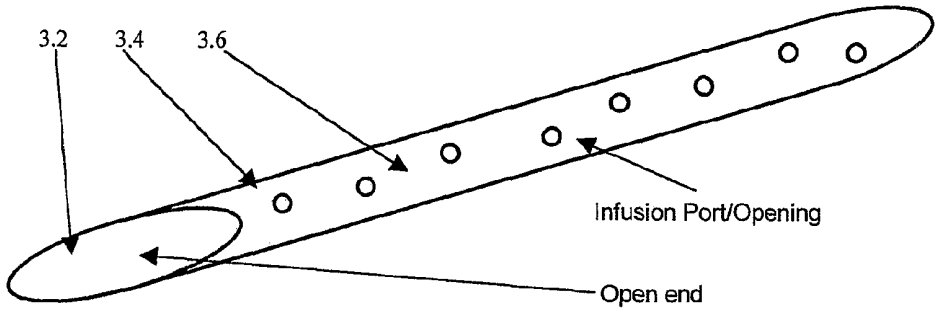


Drawnings: Wound Oxygen Cam (Oxy-Cam) (2.0)



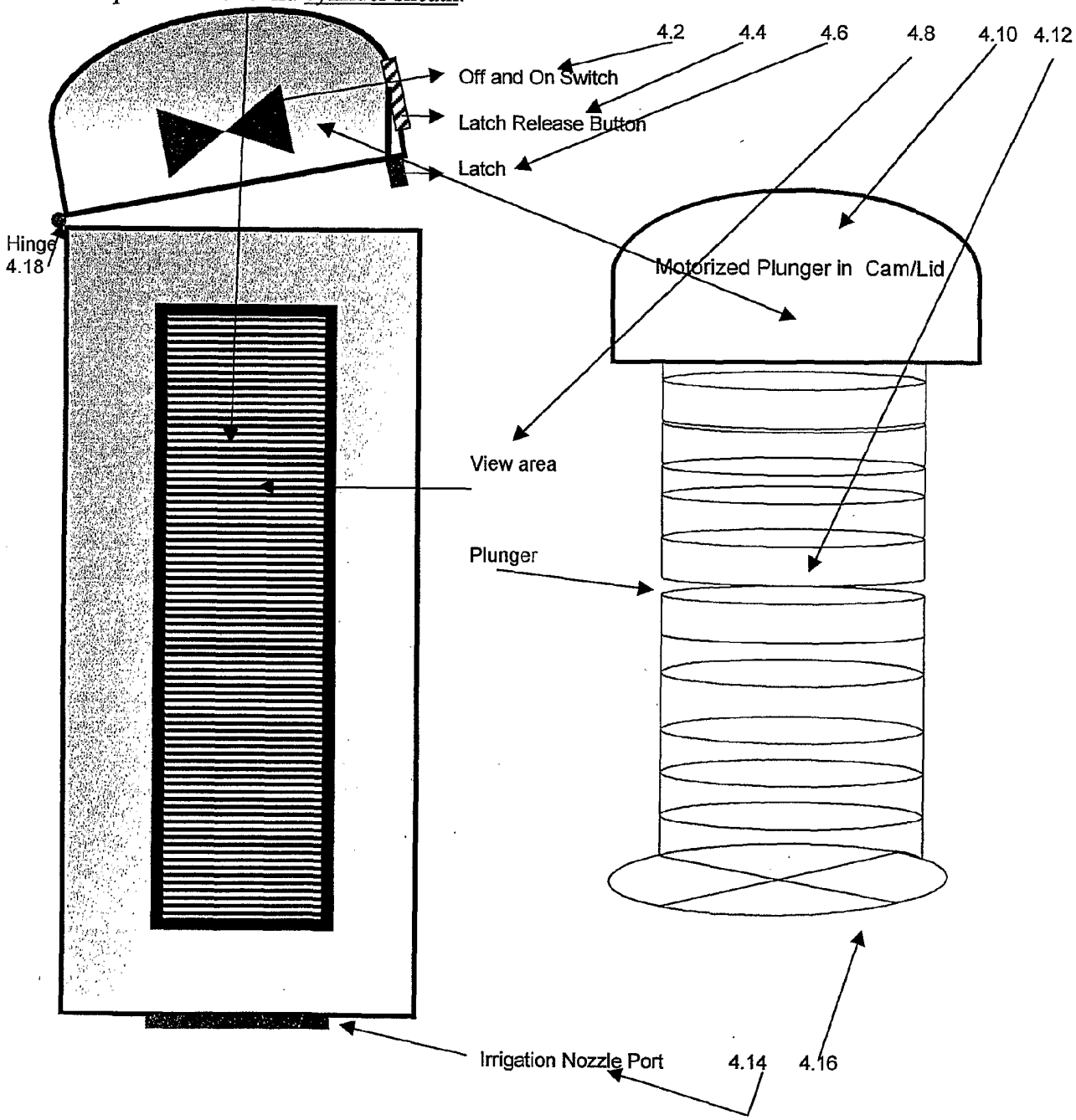
Drawnings: Wound Oxygen Infusion Canula 3.0

For use with the Wound Oxy Pad or Cam in the direct application of Oxygen to the wound surface through Macro Port or Window Wound dressings.

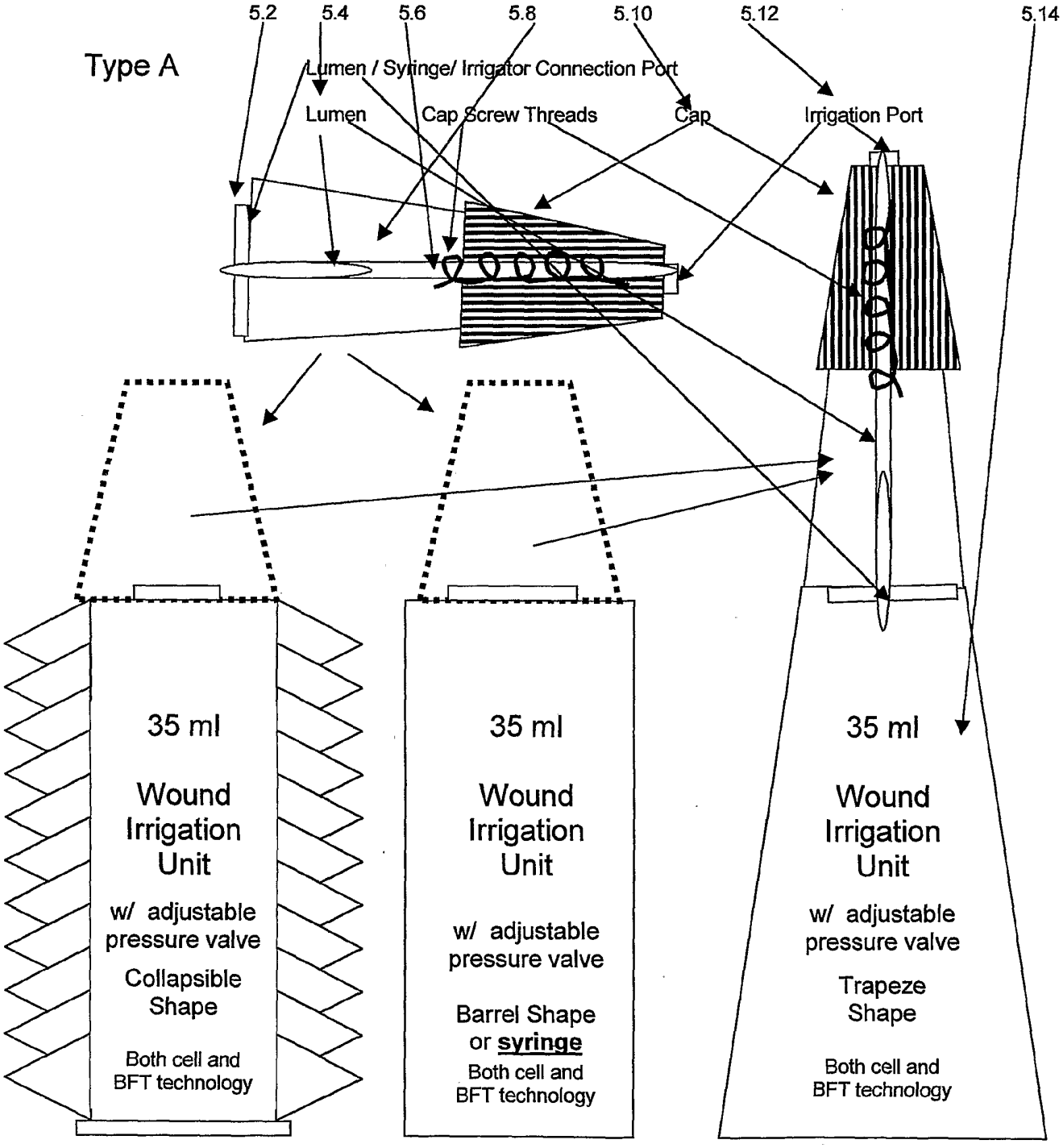


Drawnings: Mechanical (Powered) Delivery Device for Disposable Wound Irrigators. (4.0)

This unit is designed to be made out of durable plastic or suitable materials. Motorized Cam "lid" descends plunger to collapse disposable wound units that are place in the round cylinder sheath.

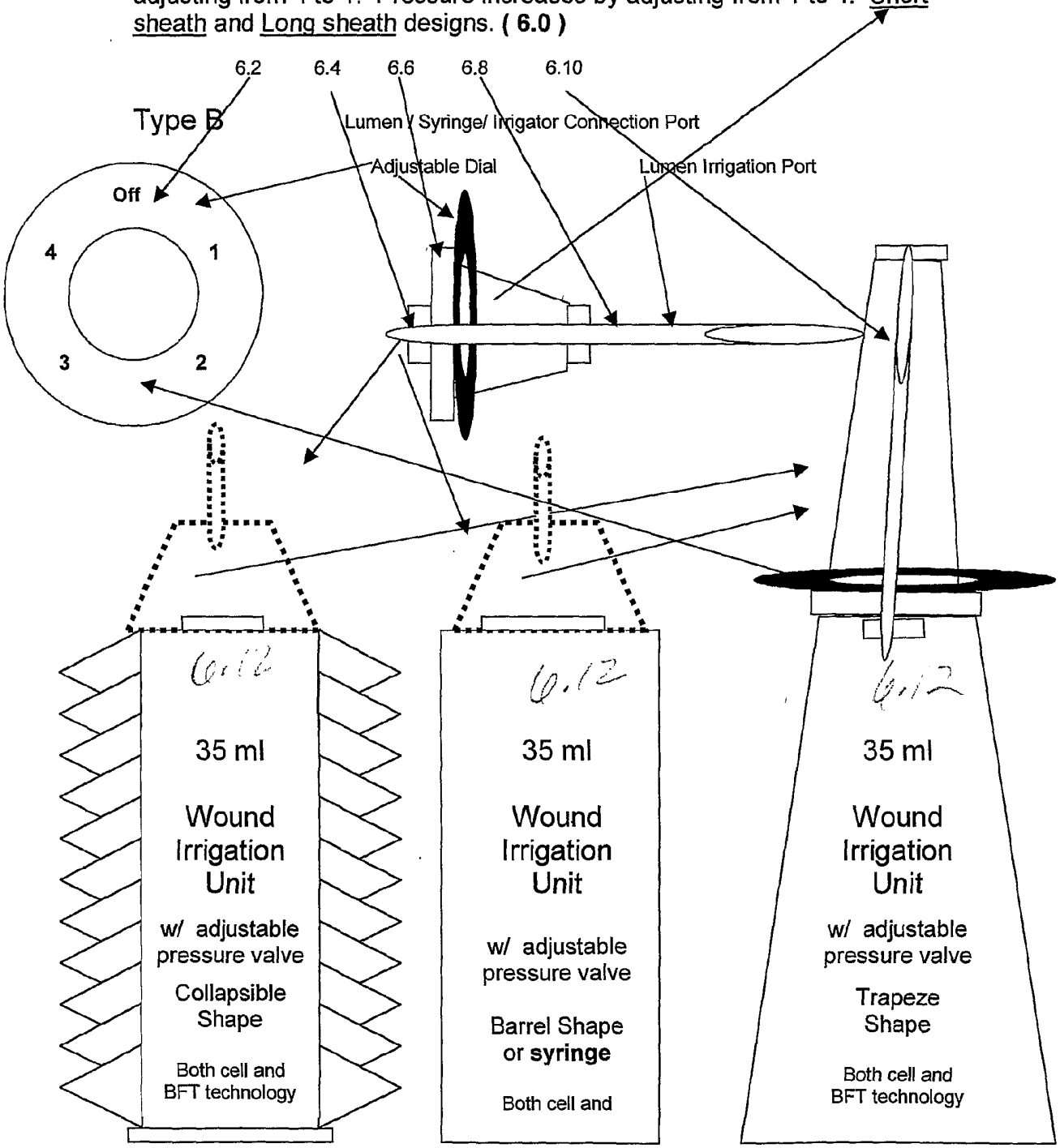


Drawnings: Adjustable Pressure Valve (Design for manufacturing as part of hand held wound irrigation unit or attachment for wound irrigation or syringe). Pressure decreases by adjusting up. Pressure increases by adjusting down. (5.0)

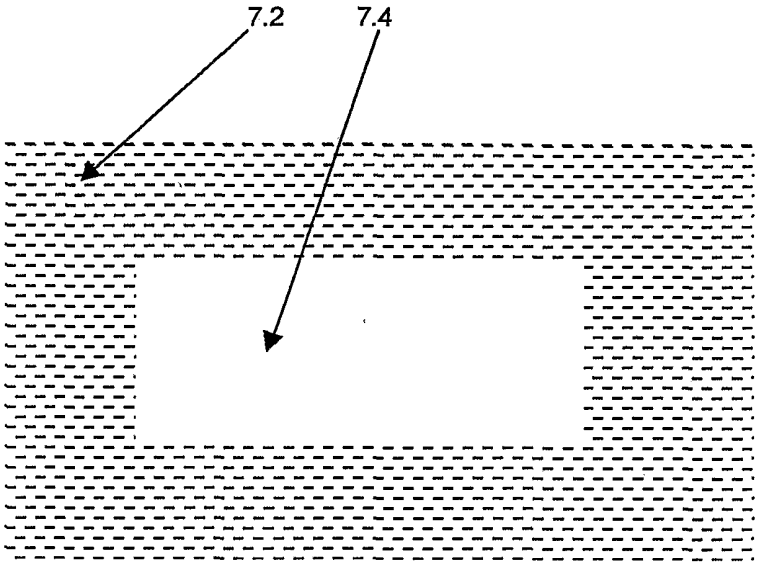


Drawnings: Adjustable Pressure Valve - Dial

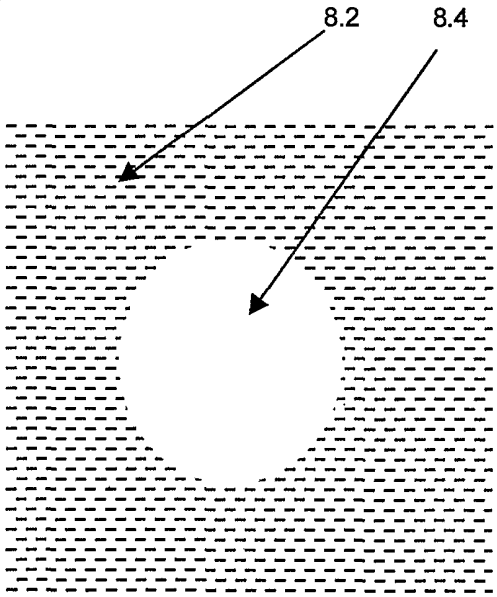
(Design for manufacturing as part of hand held wound irrigation unit or attachment for wound irrigation or syringe). Pressure decreases by adjusting from 4 to 1. Pressure increases by adjusting from 1 to 4. Short sheath and Long sheath designs. **(6.0)**



Drawnings: Oxygen Infusion Absorption Dressing for Wound Oxy-Pad. (7.0)



Drawnings: Oxygen Infusion Absorption Dressing for Wound Oxy-Cam (8.0)



Wound Irrigation Kits :

Patent Pending **Docket #: 17254.05**

Kit Number	Items Contained	Tech Route
1 BFS or CELL	(1) wound irrigator (4) 4x4 gauze (1) Sterile barrier (1) wound irrigation tray (w or w/o) Gloves	Contract Manufacturing
2 BFS or CELL w/ catheter	(1) wound irrigator (6) 4x4 gauze (1) Sterile barrier (1) wound catheter (1) wound irrigation tray (w or w/o) Gloves	Contract Manufacturing
3 BFS or CELL w/ cleanser	(1) wound irrigator (8) 4x4 gauze (1) Sterile barrier (1) pkg. wound cleanser (1) wound irrigation tray (w or w/o) Gloves	Contract Manufacturing
4 BFS or CELL w/catheter&clean	(1) wound irrigator (8) 4x4 gauze (1) Sterile barrier (1) wound catheter (1) pkg. wound cleanser (1) wound irrigation tray (w or w/o) Gloves	Contract Manufacturing
5 BFS or CELL Deep System 2	(2) wound irrigator (8) 4x4 gauze (1) Sterile barrier (1) wound catheter (1) pkg. wound cleanser (1) wound irrigation tray (w or w/o) Gloves	Contract Manufacturing W/O cath & cleanser W/ catheter W/ cleanser W/ both cath & cleanser
6 BFS or CELL Deep System 3	(3) wound irrigator (8) 4x4 gauze (1) Sterile barrier (1) wound catheter (1) pkg. wound cleanser (1) wound irrigation tray (w or w/o) Gloves	Contract Manufacturing W/O cath & cleanser W/ catheter W/ cleanser W/ both cath & cleanser
7 BFS or CELL Deep System 4	(4) wound irrigator (8) 4x4 gauze (1) Sterile barrier (1) wound catheter (1) pkg. wound cleanser (1) wound irrigation tray (w or w/o) Gloves	Contract Manufacturing W/O cath & cleanser W/ catheter W/ cleanser W/ both cath & cleanser